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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,541	12/29/2003	Vibeke Strand	252312007900	8533

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EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/748,541

Applicant(s)

STRAND ET AL.

Examiner

G. R. Ewoldt, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 7,10,17,23,29 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8,9,11-16,18-22,24-28,30-35 and 37-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

1. Applicant's election without traverse of Group I, Claims 1-38 and 40, and the species of dsDNA epitope SEQ ID NO:1, filed 11/14/06, is acknowledged.

Upon reconsideration Claim 39 is rejoined.

Claims 7, 10, 17, 23, 29, and 36 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected species.

Claims 1-6, 8, 9, 11-16, 18-22, 24-28, 30-35, and 37-40 are under examination.

2. The title is objected to because it does not adequately describe the claimed invention. Applicant is advised that a title commensurate in scope with the invention of the instant claims is required. See MPEP 608.01(b).

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 39 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The claim recites a method for stabilizing or improving the quality of life of an SLE patient comprising selecting an SLE patient and administering a treatment. The omitted steps comprise some sort of recitation of what the treatment comprises.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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6. Claims 1-6, 8, 9, 11-16, 18-22, 24-28, 30-35, and 37-40 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/41813 (IDS).

WO 01/41813 teaches a method of stabilizing or improving the health-related quality of life of an individual with SLE comprising administering LJP-394. LJP-394 comprises the dsDNA epitope of SEQ ID NO:1 conjugated to the valency platform of Claim 7 (see particularly the Claims). The reference teaches the additional limitations of the claims including sustained reduction of symptoms for at least about 24 weeks and stabilization after renal flare (Figures 14 and 15). Note that Claims 11, 12, 30, and 38 do not recite the actual use of SF-36 to measure stabilization or improvement but only that said stabilization of improvement is detectable, i.e., could be detected, employing said form. Accordingly said claims are included in the rejection.

The reference clearly anticipates the claimed invention.

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-6, 8, 9, 11-16, 18-22, 24-28, 30-35, and 37-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-64 of U.S. Patent No. 7,081,242. Although the

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conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '242 patent recite a method of treating SLE employing the GTGTGTGTGTGTGTGTGTGT sequence of SEQ ID NO:1.

9. Claims 1-6, 8, 9, 11-16, 18-22, 24-28, 30-35, and 37-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-26 of U.S. Patent Application No. 10/814,555. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '555 application recite a method of treating SLE employing the GTGTGTGTGTGTGTGTGTGT sequence of SEQ ID NO:1.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 1-6, 8, 9, 11-16, 18-22, 24-28, 30-35, and 37-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-39 of U.S. Patent Application No. 11/081,309. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '309 application recite a method of treating SLE employing the GTGTGTGTGTGTGTGTGTGT sequence of SEQ ID NO:1.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 1-6, 8, 9, 11-16, 18-22, 24-28, 30-35, and 37-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-27 of U.S. Patent Application No. 11/347,426. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '426 application recite a method of treating SLE employing the GTGTGTGTGTGTGTGTGTGT sequence of SEQ ID NO:1.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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12. Claims 1-6, 8, 9, 11-16, 18-22, 24-28, 30-35, and 37-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-21 and 34-55 of U.S. Patent Application No. 11/373,699. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '699 application recite a method of treating SLE employing the GTGTGTGTGTGTGTGTGTGT sequence of SEQ ID NO:1.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 1-6, 8, 9, 11-16, 18-22, 24-28, 30-35, and 37-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-26 of U.S. Patent Application No. 11/565,467. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '467 application recite a method of treating SLE employing the GTGTGTGTGTGTGTGTGTGT sequence of SEQ ID NO:1.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. Claims 1-6, 8, 9, 11-16, 18-22, 24-28, 30-35, and 37-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-21 and 34-55 of U.S. Patent Application No. 11/613,987. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '987 application recite a method of treating SLE employing the GTGTGTGTGTGTGTGTGTGT sequence of SEQ ID NO:1.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

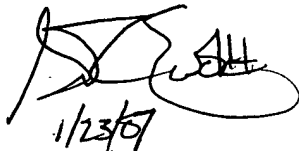
15. No claim is allowed.

16. Applicant is reminded of the duty to disclose **ALL** information material to patentability, as set forth in 37 CFR 1.56, including **ALL** applications, including those subsequently filed, claiming the same invention as the instant application.

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17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571)272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

18. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.



1/23/07

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Primary Examiner
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